

REMARKSClaim rejection – 35 U.S.C. §112

Claim 1 is rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 1 is directed to an oral pharmaceutical formulation comprising at least one bisphosphonate and one or more additive agent. One such additive agent is a lipid. In the Amendment, filed September 17, 2002, claim 1 was amended to provide that "a medium chain glyceride or a mixture of medium chain glycerides" is excluded from the class of lipids which is included within the scope of the claimed invention.

In the final Office Action, the Examiner alleges that the specification does not teach the exclusion of a medium chain glyceride or a mixture of medium chain glycerides. It is the Examiner's opinion that the specification discloses that medium chain glycerides or a mixture of medium chain glycerides is a preferred embodiment of the claimed invention. Applicants respectfully disagree for the following reasons.

The disclosure appearing in the specification at page 4, lines 27-28 provides that the lipids disclosed in PCT application No. SE98/01790 *are excluded* from the claimed invention. A definition of the lipids disclosed in PCT application No. SE98/01790 is set forth in the specification at page 6, lines 12-19. Specifically, it is disclosed that:

Lipids referred to above as disclosed in PCT application no SE 98/01790 are a medium chain glyceride or a mixture of medium chain glycerides.... (p. 6, lines 12-13).

Thus, when the respective disclosures appearing on page 4, lines 27-28, and page 6, lines 12-12, are read together, it is evident that the exclusion of medium chain glycerides and mixtures thereof was described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, as defined by claim 1.

At page 6, line 3, it is disclosed that preferred additives of the claimed invention includes lipids, such as a phospholipid, e.g., DPPC and DMPC. Phospholipids, including DPPC and DMPC, are *not* medium chain glycerides. Therefore, this disclosure of a preferred embodiment is consistent with the exclusion of medium chain glycerides and mixtures thereof which was set forth in the application as originally filed.

Finally, none of the Examples discloses a formulation comprising a bisphosphonate and a medium chain glyceride. Moreover, *original* claim 1 expressly excludes medium chain glycerides and mixtures thereof, particularly those having the recited formula as disclosed in PCT application No. PCT/SE98/01790 and having the recited formula.

For all of the foregoing reasons, therefore, Applicants respectfully submit that the §112, first paragraph, rejection is improper and withdrawal thereof is respectfully requested.

Applicants wish to bring the Examiner's attention to certain inadvertent clerical errors which appear in the specification and which apparently went unnoticed at the time of filing. At page 5, lines 15-24, combinations of additives are disclosed. From this disclosure, it appears that lipids and non-lipids, including those disclosed in the PCT application No. PCT/SE98/0179, are included within the scope of the invention. However, the disclosure at page 5, lines 15-24 is inconsistent with the overwhelming weight of evidence that the claimed invention (See original claim 1) excludes medium chain glycerides and mixtures thereof (See page 4, lines 27-28; page

6, lines 12-12; and the Examples). Moreover, at page 5, lines 19-20, medium chain glycerides are incorrectly characterized as an example of a phospholipid. The person of ordinary skill in the art knows that a phospholipid is not a medium chain glyceride.

Notwithstanding the unintentional clerical errors appearing in the specification at page 5, lines 15-24, withdrawal of the §112 rejection is proper when original claim 1 and the specification, as originally filed, is considered in its entirety.

The office Action provides that claims 2-21, 23, 40-42 and 45-46 are objected to as being dependent on a rejected claims. The claim objection will become moot upon withdrawal of the §112 rejection.

The Examiner's attention is also directed to claim 47 which was introduced by the Preliminary Amendment, filed October 5, 2001.

CONCLUSION

Applicants submit that the remarks are fully responsive to the Office Action. Pending claims 1-21, 23-34, 40-42 and 45-47 are in condition for allowance, which action is earnestly solicited. The Assistant Commissioner is hereby authorized to charge Deposit Account No. 23-1703 in the event that any fee is required in connection with this communication..

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Respectfully submitted,



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